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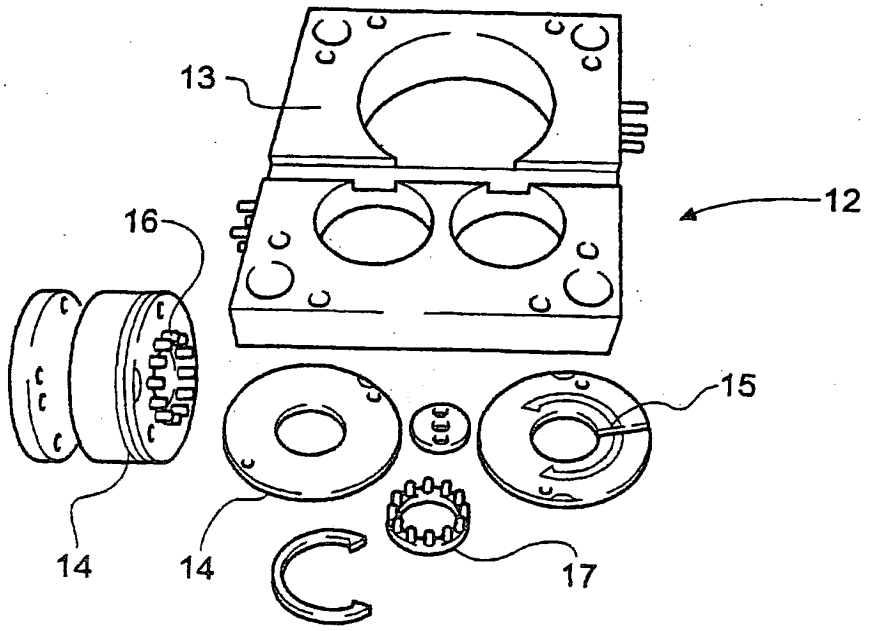
(54) Title: MODULAR MOULD TOOLS



(57) Abstract: There is described a modular bolster set provided with stackable plates which can be stacked together to form a cavity for the device. There is also described a method of manufacturing a medical device which comprises the use of a modular bolster set.

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MODULAR MOULD TOOLS

This invention relates to a novel tooling method and novel process for use of such tools.

Traditionally, the only option available to designers and engineers when designing plastics components has been to work from fabricated components produced from bulk material supplied in sheet or bar stock. However, there are many problems associated with fabricating plastics parts, which make this route less than ideal. For example, not all materials are available in sheet stock, flexible hinges and springs can be difficult to reproduce and small features can be difficult to fabricate. Therefore fabricated parts have been typically used to produce proof of concept models only. Designers have then had to of design and manufacture pre-production mould tooling before being able to complete the design and proof of concept stages. These pre-production mould tools are normally scaled-down versions of the final production tools and can take up to 20 weeks to produce.

More recently, with the advent of techniques such as stereolithography, it has been possible to produce one-off models which can be used as "masters" for resin moulds which can allow small volumes of parts to be produced. However, the number of materials which can be produced in this way is limited and this technique is best suited to development of proof of concept models only.

Conventionally, production mould tools can normally be divided into three sections:

(i) a cavity/cavities which represent the form of the component to be produced;
(ii) a fixed half which includes the feed system; and
(iii) a moving half which includes the ejection system.

The purpose of these moulds is to allow for the production of high volume, low-cost components on automated injection mould machines. However, these tools are often

complex and modifications can be difficult to make if further optimisation of the design is required.

With the ever-increasing need to reduce the time taken to commercialise new products, it is essential that a multifunctional approach is taken to the development of medical devices, such as inhalers. This means that teams of designers, engineers and scientists must work together from the early stages of product development to ensure that the final inhaler design is suitable for and available for use in pivotal clinical trials.

Traditional tooling is considered an obstacle to rapid development of devices, owing to the long lead times in production and the difficulties associated with easy modification of these types of tools.

The development of new devices demands a multifunctional approach from designers, engineers, scientists and clinicians. Design and rapid engineering of prototypes represents the first critical step in this process. We have now found a novel tooling technique based on the manufacture of hard tools composed of plates or segmental parts permits prototyping to be conducted quickly and economically, using material relevant to the potential unique interplay, such as electrostatic interactions, between specific drug substances/excipients and specific plastic materials. A further advantage of this technique is the ability to easily modify tools as device prototypes are refined.

We have developed a novel solution to the problems involved in a rapid production of hardened mould tooling.

Thus according to the invention we provide an injection moulding system comprising a modular bolster set provided with at least a pair of plates which can be stacked together to form a cavity, the plates include a feed and ejection system; and a cavity moulding set adapted for moulding of an article.

The injection moulding system of the invention is especially suitable for the manufacture of small plastics devices e.g. medical devices, such as an inhalation device. The inhalation device manufactured by the system of the invention may comprise any conventionally known inhalation device, for example, a metered dose inhaler (MDI) and especially, a dry powder inhaler (DPI). Examples of DPIs which may be mentioned are those currently available from Innovata Biomed in the UK under the Trade Marks CLICKHALER® and TECHNOHALER®. CLICKHALER is described in International Patent application No. WO 92/00771, which is incorporated herein by reference. TECHNOHALER is described in International Patent application No. WO93/16748 which is incorporated herein by reference.

The cavity moulding set used in the system of the invention preferably comprises an assembly of plates and segments. The plates are preferably wire eroded plates.

According to a further feature of the invention we provide a method of manufacturing a plastics device which comprises injecting a molten plastics material into an injection moulding system as hereinbefore described.

We further provide a plastics device manufactured by the method described above. The plastics device may be a medical device, such as an inhalation device e.g. a DPI.

In one embodiment of the invention the method comprises the manufacture of a CLICKHALER, for example, an inhaler comprising a body defining a storage chamber for a substance to be delivered and further defining an inhalation passage through which air is drawn via the mouthpiece; a metering member operable to transfer a volumetric dose of the substance from the storage chamber to the inhalation passage, the metering member having a metering surface which is indented to provide at least one dispensing cup and being moveable between a first position in which a dispensing cup is presented to the inhalation passage wherein in the second position the dispensing cup is upwardly open , the inhaler comprising cup clearing

means which comprises means for moving each dispensing cup into a position form which any of the substance remaining in the dispensing cup would tend to fall, under the influence of gravity, out of the cup, after a dose of the substance has been presented in the cup to the inhalation passage and before the cup id again presented to the storage chamber.

In a further embodiment of the invention the method comprises the manufacture of a TECHNOHALER, for example, apparatus for dispensing a plurality of desired volumetric doses of a flowable substance comprising a storage chamber for the substance and an outlet conduit communicating with the chamber, characterised by a plurality of metering devices, each metering device having first and second end elements adapted to seal against the inner walls of the conduit so as to define an intermediate dosing space of the desired dose volume and means for advancing the metering devices in series from within the storage chamber into the outlet conduit so as to cause substance surrounding each device in the storage chamber to pass with the device into the conduit in the respective dosing space.

The novel method of the invention resolves the difficulties involved with fabrication and the lead-times in producing traditional mould tools is to strip away the complex ejection and feed systems used in hardened mould tools. These are replaced with a modular bolster set which contains a common feed system and takes a cavity set which is assembled from wire eroded plates and segments.

In use the cavity moulding set may be assembled by hand and loaded into the modular bolster set whilst in the press. Material e.g. plastics can then be then injected into the tool. When cooled the entire cavity moulding set removed by hand. The plates can then be dismantled, the component removed, the cavity reassembled and the process repeated. The use of wire eroding allows plate mould tools to be produced rapidly with simple parts taking less than one day and even very complex forms taking only a week.

The main advantages of this system are that parts can be moulded in the relevant production materials, designers can test and modify the moulded parts very quickly and finished devices can be assembled rapidly for early trials. Furthermore the pre-production tools can be produced with confidence as the moulded part has been tested, reducing the tooling development time.

The method of invention is especially suited to the manufacture of small plastics medical devices, such as an inhalation device.

The method of the invention is advantageous in that;

it allows complex models to be made using injection moulded parts;

it allows devices to be tested and refined without the need for producing pre-production moulds;

it permits early testing to be conducted using the final materials avoiding problems with material compatibility; and

it offers considerable cost and time saving over traditional methods.

The invention will now be described by way of example only and with reference to the accompanying drawings in which Figure 1 is a moulding tool of the prior art; and

Figure 2 is a perspective view of a cavity injection moulding system of the invention.

Referring to Figure 1, an injection moulding system (1) of the prior art comprises a moving half (2) and a fixed half (3). The fixed half (3) is provided with an injection point and runner (4) and a component cavity (5). The moving half (2) is provided with an ejection point (6). The moving half (2) is also provided with a female connector (7) at each corner (8) adapted to engage with corresponding male connections (9) situated at each corner (10) of the fixed half (3). A plastics component (11) is also shown.

Referring to Figure 2, a modular bolster set (12) comprises a tool block (13) and a plurality of stackable cavity plates (14) provided with an injection point and runner (15) and ejection pins (16). A plastics component (17) is also shown.

Example 1 CLICKHALER

An initial design was prepared on CAD and plate mould tools were produced of the three new components required in the new design. From these parts minor changes were made to the positions of the gear teeth and flexible ratchet fingers. Within one month working models of the new design had been prepared which were suitable for laboratory testing to confirm shot weight performance and dose consistency of the new inhaler design. The component designs were then produced in fully hardened cavities for use in a modular bolster system allowing for the production of devices for clinical trials; the whole programme taking approximately three months.

Example 2 TECHNOHALER

TECHNOHALER is a new multi-unit dose powder inhaler currently under development by Innovata Biomed. The TECHNOHALER has a unique system for dispensing the powder, which allows a strip of spools to be pre-filled at the factory and then dispensed from a carousel in the device. This ensures a high accuracy in dosing as well as adding moisture protection to the individual dose. Proof of concept models were produced using the plate moulding technique described earlier. The availability of working prototypes of the device mechanism and casing allowed the engineering team to evaluate the design without the need for production of expensive pre-production mould tools.

CLAIMS

1. A modular bolster set provided with stackable plates which can be stacked together to form a cavity for the device.

2. A modular bolster set according to claim 1 characterised in that it is adapted for the manufacture of an inhalation device.

3. A modular bolster set according to claim 2 characterised in that the inhalation device is a dry powder inhaler (DPI).

4. A modular bolster set according to claim 3 characterised in that the inhalation device is a CLICKHALER.

5. A modular bolster set according to claim 1 characterised in that that the inhalation device is a TECHNOHALER.

6. A method of manufacturing a medical device which comprises the use of a modular bolster set according to claim 1.

7. A method according to claim 6 characterised in that the medical device is an inhaler comprising a body defining a storage chamber for a substance to be delivered and further defining an inhalation passage through which air is drawn via the mouthpiece; a metering member operable to transfer a volumetric dose of the substance from the storage chamber to the inhalation passage, the metering member having a metering surface which is indented to provide at least one dispensing cup and being moveable between a first position in which a dispensing cup is presented to the inhalation passage wherein in the second position the dispensing cup is upwardly open , the inhaler comprising cup clearing means which comprises means for moving each dispensing cup into a position form which any of the substance remaining in the dispensing cup would tend to fall, under the influence of gravity, out

of the cup, after a dose of the substance has been presented in the cup to the inhalation passage and before the cup id again presented to the storage chamber.

8. A method according to claim 6 characterised in that the medical device is an apparatus for dispensing a plurality of desired volumetric doses of a flowable substance comprising a storage chamber for the substance and an outlet conduit communicating with the chamber, characterised by a plurality of metering devices, each metering device having first and second end elements adapted to seal against the inner walls of the conduit so as to define an intermediate dosing space of the desired dose volume and means for advancing the metering devices in series from within the storage chamber into the outlet conduit so as to cause substance surrounding each device in the storage chamber to pass with the device into the conduit in the respective dosing space.

9. The use of a modular bolster set according to claim 1 in the manufacture of a medical device.

10. A modular bolster set substantially as described with reference to the accompanying description and drawings.

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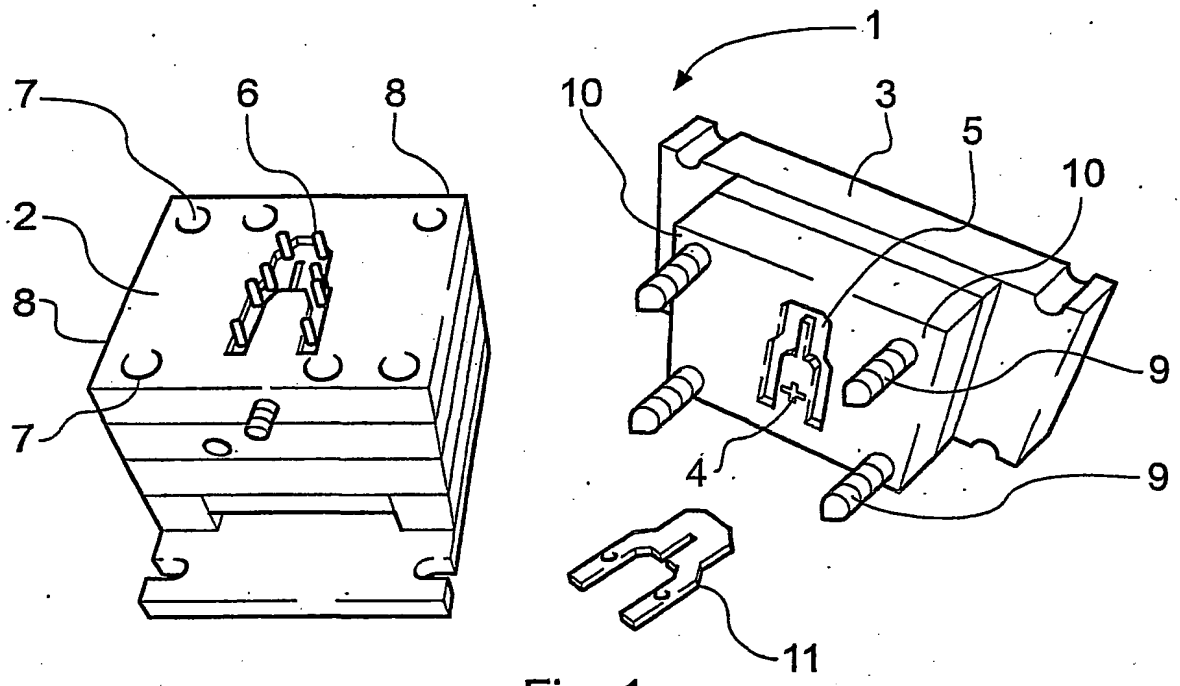

Fig. 1

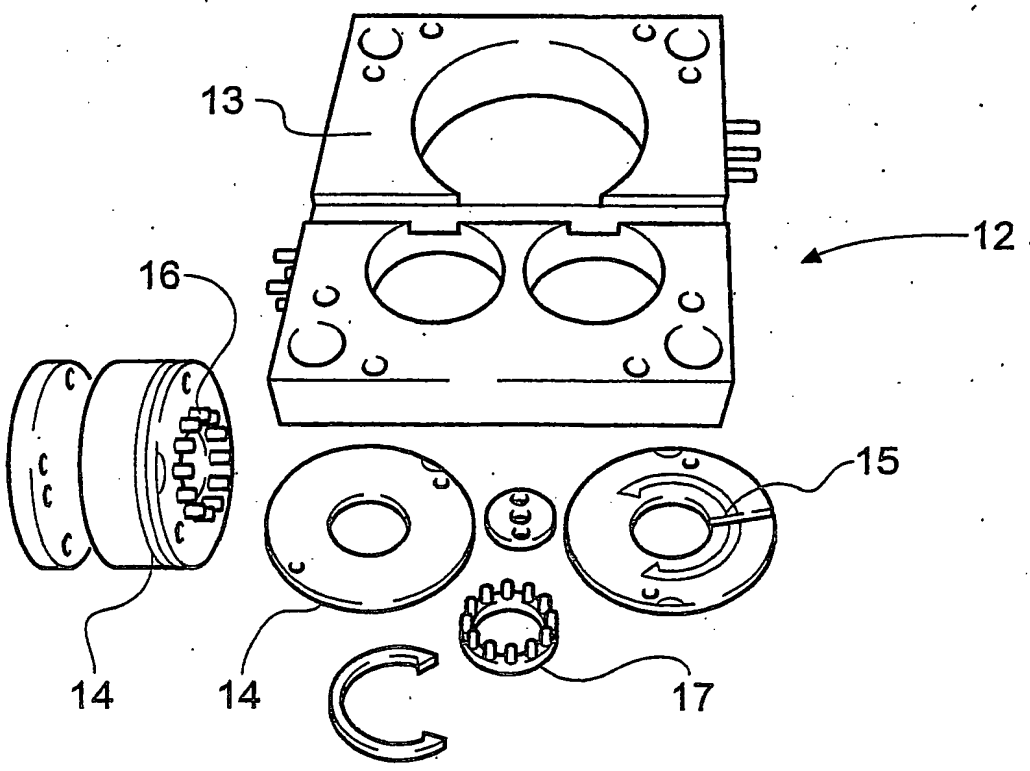

Fig. 2

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 B29C45/37

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 B29C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 792 297 A (WILSON JEROME L) 20 December 1988 (1988-12-20) column 5, line 18 - line 31; figure 7 column 6, line 6 - line 20 ---	1,10
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search	Date of mailing of the international search report
30 May 2001	08/06/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Bollen, J

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